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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/664,473	09/18/2000	Hugh Sharkey	17616-842	6257

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EXAMINER

SHAY, DAVID M

ART UNIT

PAPER NUMBER

3739

DATE MAILED: 03/04/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/064473

Applicant(s)

Shankar et al

Examiner

d-shay

Group Art Unit

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—The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address—

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE —3— MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

- ☒ Responsive to communication(s) filed on September 18, 2000
- ☒ This action is FINAL.
- ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- ☒ Claim(s) 50-56 is/are pending in the application.
- Of the above claim(s) _____ is/are withdrawn from consideration.
- ☐ Claim(s) _____ is/are allowed.
- ☒ Claim(s) 50-56 is/are rejected.
- ☐ Claim(s) _____ is/are objected to.
- ☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been received.
- ☐ received in Application No. (Series Code/Serial Number) _____
- ☐ received in this national stage application from the International Bureau (PCT Rule 1.7.2(a)).

*Certified copies not received: _____

Attachment(s)

- ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
- ☒ Notice of Reference(s) Cited, PTO-892
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Interview Summary, PTO-413
- ☐ Notice of Informal Patent Application, PTO-152
- ☐ Other _____

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It is noted that the claims as amended by the pre-amendment are substantially those claims being prosecuted in U.S. Patent Application number 08/696,051 and it is further noted that these claims were submitted without further argument drawn to their patentability over the prior art applied thereto in the parent case. Therefore, the rejections and answers to arguments set forth in the parent will be herein repeated as applied to the instant claims.

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 54-56 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 54-56 appear to be substantial duplicates, as it is unclear how the compositions use affects the structure thereof.

- a. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this

Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

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The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) do not apply to the examination of this application as the application being examined was not (1) filed on or after November 29, 2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

3. Claims 50-56 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Sand ('709).

4. Claims 50-56 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Sand ('169).

Sand ('709) discloses that ligaments and tendons are collagenous bodies (see column 1, lines 25-28); the known shrinkage properties of collagen (see column 1, lines 50-53), and the discloses the use of the method on collagenous tissues throughout the body (see column 1, lines 62-68). Sand ('169) discloses all of the above and additionally discusses the relative shrinkage temperature of tendon collagen specifically.

Regarding claims 54-56, the Examiner has maintained the rejection because the "starting material" applicant uses are not differentiated in terms of their treatment in the instant specification or the prior art of record.

Applicant notes the interview summary penned by the Examiner on December 10, 1997. The Examiner regrets that the Sand ('709) reference had not been reviewed with sufficient thoroughness when the interview was held. However, neither the statement by the Examiner nor applicant's arguments can

remove from Sand ('709) the teachings which appear therein in black and white.

It is undeniable that Sand ('709) heating thereof. Sand ('709) teaches the shrinkage of corneal collagen by controlled, begins, stating "collagen connective tissue is ubiquitous in the human body and... provides the cohesiveness and tenacity of the musculosp^{skeletal}heletal system, the structural integrity of the viscera, as well as the elasticity of the integument "(see Sand ('709) column 1, lines 15-20).

Sand ('709) continues: "The walls of the great vessels share their collagen integrity with the ligamentous bony attachments and the tendinous or sinewy muscular attachments..." (column 1, lines 25-28). "The present invention is directed to a method and apparatus for effecting controlled lineal contraction or shrinkage of collagen fibers to provide a multitude of nondestructive and beneficial structural changes and corrections within the body. The invention has application to the alternation of collagen connective tissue throughout the body and will be described with specific reference to correction of refractive disorders of the cornea of the eye. "(emphasis, added, column 1, line 62 – column 2 line 2). Lastly, Sand (709) states "while disclosed as a corneal shape-modifying technique the system has application to other collagenous bodies, and is believed useful in fields ranging from cosmetic surgery to correction of defective heart valves or musculoskeletal injuries" (column 8, line 67 – column 9, line 3).

The Examiner notes applicants arguments that terms such is "tendon" and "ligament" do not appear in Sand. However, though the recitations do not

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appear *ipsis verbis*, the recitation at column 1, lines 25-28 is clearly a teaching to use these starting materials. The examiner again regrets his inadequate review of the Sand ('709) reference. However, it is noted that this reference was also available to applicant and a more thorough review thereof on applicant's part could have avoided this unfortunate chain of events as well.

Regarding the arguments filed with the after final amendment filed May 19, 2000, the examiner notes that a simple allegation, without showing of fact, is insufficient to demonstrate non-enablement. It is further noted that Sand discusses the use of the method on tendon and ligament material, there is no discussion of tying these materials ⁿ to the method. dm

5. This is a continuation of applicant's earlier Application No. 08/696,051. All claims are drawn to the same invention claimed in the earlier application and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the earlier application. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action in this case. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

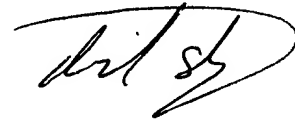
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the advisory action. In no, event , however will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication should be directed to David Shay at telephone number (703) 308-2215.

David Shay:bhw

January 17, 2002

A handwritten signature in black ink, appearing to read 'David M. Shay', enclosed within a large, stylized oval flourish.

**DAVID M. SHAY
PRIMARY EXAMINER
GROUP 330**